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510(k) SUMMARY

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DENTSPLY

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TRADE NAME: AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL

CLASSIFICATION NAME: Impression Material

PREDICATE DEVICE: AquaSil™ Smart Wetting Impression Material K943574

DEVICE DESCRIPTION: AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL is a two-part (base/catalyst) hydrophilic vinylpolysiloxane (VPS), crown and bridge impression material used to record the details of hard and soft surfaces of the oral cavity.

AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL is available in Regular Set and Fast Set. These elastomeric impression materials have excellent hydrophilic properties, dimensional accuracy, high tear strength, and resistance to permanent deformation.

AQUASIL™ RIGID SMART WETTING Regular Set and Fast Set IMPRESSION MATERIALS improve both wetting on the tooth surface and model detail reproduction.

INTENDED USE: AQUASIL™ RIGID Regular Set SMART WETTING IMPRESSION MATERIAL is designed as a firm tray material. It is designed to be used with Aquasil™ LV (light viscosity) Impression Material (K943574) in a dual phase impression Technique. The combination is ideal for the double arch (Caulk® First Bite™ Trays) dual phase technique. The combination may also be used for precise duplications of models.

AQUASIL™ RIGID Fast Set SMART WETTING IMPRESSION MATERIAL is designed as a firm tray material. It is designed to be used with Aquasil™ LV Fast Set Impression Material in a dual phase impression Technique, capturing one or two adjacent preparations. The combination is ideal for the double arch (Caulk® First Bite™ Trays) dual phase technique. The combination may also be used for precise duplications of models.

TECHNOLOGICAL CHARACTERISTICS: All of the components of AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL have been used in DENTSPLY predicate devices. The one component not found in the predicate device (K943574) has been used in DENTSPLY's legally marketed Reprosil® Impression Material (K781151A).

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TRADE NAME: AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL

Due to the similarity of the formulation of AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL to the AquaSil™ Smart Wetting Heavy Body Impression Material, we believe that additional biocompatibility testing of the new impression material is unnecessary.

The predicate device, AquaSil® Smart Wetting Impression Material, was evaluated in K943574, as outlined below:

The catalyst and base pastes and the mixed product were evaluated for cytotoxicity. The mixed product was evaluated for dermal toxicity, for irritation, and for mutagenicity.

The base pastes give a moderate cytotoxicity and the catalyst pastes were non-cytotoxic. When mixed, the cytotoxicity persisted, but was recorded as a lower value than the value for Reprosil Impression Material.

The mixed product was tested by the Ames Mutagenicity Test, Acute Dermal Toxicity Test, and the Hamster Cheek Pouch Irritation Study. The final product is non-mutagenic, non-toxic, and a non-irritant.

As crown and bridge impression materials, AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL and the predicate device (K943574) are in the mouth for, at most, ten minutes.

We believe that the prior use of the components in predicate medical devices, the results of the final product testing of the predicate device, the limited exposure time in the mouth, and the performance data outlined above support the safety and effectiveness of AQUASIL™ RIGID SMART WETTING IMPRESSION MATERIAL for the intended use.

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